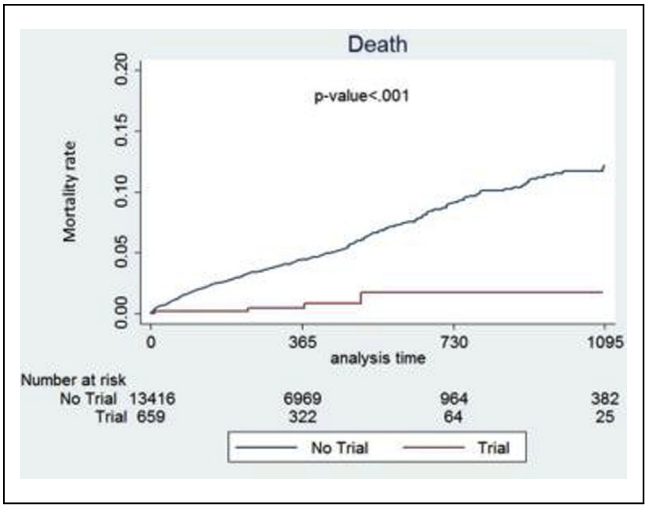
higher low density lipoprotein (LDL). These patients were less likely to have calcified lesions and more likely to have ACC/AHA Type C lesions. The MACE rate was non-significantly higher for patients enrolled in a clinical trial versus not (12.6% versus 12.2%, p = 0.8) as was TVR (6.4% versus 5.6%, p = 0.4). Patients enrolled in clinical trials had a lower mortality after PCI (0.8% versus 4%, p < .001).



CONCLUSIONS Patients enrolled in clinical trials had a lower mortality rate after PCI than those that were not. Whether this difference is due to a lower risk profile of this cohort, or the benefits associated with trial enrollment, including closer follow-up, warrants further investigation.

CATEGORIES CORONARY: PCI Outcomes

KEYWORDS Clinical outcomes, Clinical Trial

TCT-447

Real World Generalizability Of Patients Enrolled In Clinical Trials Versus Those Not Enrolled

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BACKGROUND Clinical trials in the United States tend to enroll racially homogenous cohorts, thereby limiting generalizability. We sought to identify correlates of clinical trial enrollment from a large and racially diverse PCI registry.

METHODS We conducted a single-center study of patients undergoing PCI between 1/1/2010 and 12/31/2013 (n=14,075) at the Mount Sinai Medical Center. We compared demographic, clinical and procedural characteristics between patients who were and were not enrolled in clinical trials during this period. Independent correlates of trial enrollment were identified using multivariable logistic regression.

RESULTS Patients enrolled in trials (n=659, 4.69%) were younger and more likely to present with stable clinical syndromes compared to their counterparts not enrolled (n=13,416, 95.32%). African-Americans and Hispanics were more frequently enrolled while Asians were less likely to enter trials compared to Caucasians. In terms of PCI procedural characteristics, the enrolled cohort was less likely to undergo PCI of a saphenous vein graft and have thrombotic lesions (Table).

Table. Baseline and procedural characteristics of patients enrolled in clinical trials versus not at Mount Sinai Hospital, New York.

	p value	Odds ratio	95% Confidence Interval
Age	0.001	0.98	0.97-0.99
Hispanics	0.042	1.32	1.01-1.73
Prior MI	0.046	0.74	0.55-0.99
Dialysis	0.015	0.23	0.07-0.76
STEMI	0.005	0.16	0.04-0.57
PCI-SVG	0.018	0.09	0.01-0.66
Thrombosis	0.011	1.98	1.17-3.36

MI: Myocardial Infarction; PCI-SVG: Percutaneous Coronary Intervention- Saphenous Vein Graft; STEMI: ST-Segment Elevation Myocardial Infarction

CONCLUSIONS Patients enrolled in clinical trials differ substantially from those not enrolled in terms of their baseline demographics, clinical presentation, and procedural parameters, highlighting the limited generalizability of trial results to real-world populations.

CATEGORIES OTHER: Statistics and Trial Design

KEYWORDS Clinical Trial

TCT-448

Differential Prognostic Impact between 1st and 2nd Generation Drug-Eluting Stents in Coronary Bifurcation Lesions: Patients-Level Analysis of the Korean Bifurcation Pooled Cohorts

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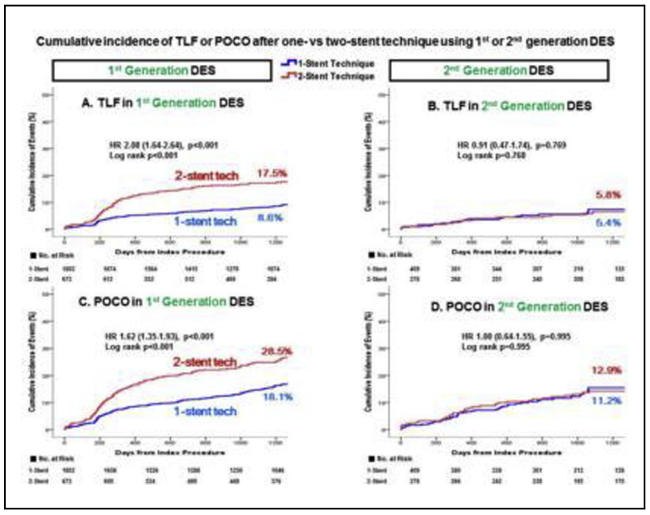
BACKGROUND The 2-stenting technique has been regarded to show worse clinical outcomes than the 1-stenting technique after bifurcation PCI with 1st generation DES. However, there has been paucity of data comparing 1- and 2-stenting techniques with the use of 2nd generation DES. Therefore, we sought to investigate the differential clinical outcomes after PCI for coronary bifurcation lesions with 1- or 2-stenting techniques using 1st or 2nd generation drug-eluting stent (DES).

METHODS Patient-level pooled analysis was performed with 3,162 patients undergoing PCI using 1st or 2nd generation DES for bifurcation lesions from the 'Korean Bifurcation Pooled Cohorts' (COBIS II, EXCELLENT, and RESOLUTE-Korea registry). The 3-year clinical outcomes were compared between 1- and 2-stenting techniques, stratified by the type of DES.

RESULTS With 1st generation DES, rates of target lesion failure (TLF) or patient-oriented composite outcome (POCO, a composite of all death, any MI, any repeat revascularization, and cerebrovascular accidents) at 3-year were significantly higher after 2-stenting than 1-stenting technique (TLF: 8.6% vs. 17.5%, p<0.001; POCO 18.1% vs. 28.5%, p<0.001). With 2nd generation DES, however, there was no difference between 1- and 2-stenting techniques (TLF: 5.4% vs. 5.8%, p=0.768; POCO: 11.2% vs. 12.9%, p=0.995). The differential impacts of 2-stenting technique on the prognosis according to the type of DES were also corroborated with similar results by the inverse probability weighted model. The 2-stenting technique was a significant independent predictor of TLF in 1st generation DES (HR 2.046, 95% CI 1.114-3.759, p<0.001), but not in 2nd generation DES (HR 0.667, 95% CI 0.247-1.802, p=0.425).



CONCLUSIONS Our patient-level pooled analysis of 3-years clinical results of 3,162 patients in Korean Bifurcation Pooled Cohorts demonstrated that 2-stenting technique showed comparable outcomes to 1-stenting with 2nd generation DES, which is different from the results of 1st generation DES favoring 1-stenting technique. Such an improved performance of 2nd generation DES even after complex technique for bifurcation lesions may provide room for more aggressive approach for the selected bifurcation lesions with appropriate anatomy, rather than universal application of the 1-stenting strategy.

CATEGORIES CORONARY: PCI Outcomes

KEYWORDS Bifurcation lesion, Bifurcation stenting, Clinical outcomes

TCT-449

Percutaneous Coronary Intervention at Centers With and Without On-Site Surgical Backup: An Updated Meta-analysis of 23 Studies

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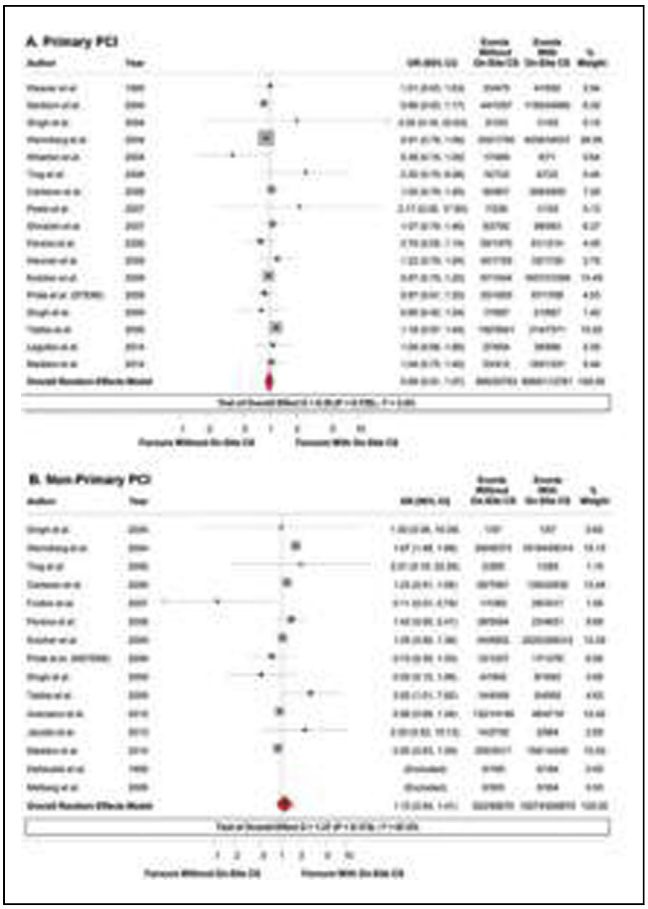
BACKGROUND Emergency coronary artery bypass grafting (CABG) for unsuccessful percutaneous coronary intervention (PCI) is now rare. We aimed to evaluate the current safety and outcomes of primary PCI and non-primary PCI at centers with and without on-site surgical backup.

METHODS We performed an updated systematic review and meta-analysis using mixed-effects models. Randomized controlled trials (RCT) or prospective observational studies with adjustment of baseline differences, which compared all-cause mortality or emergency CABG rates of PCI performed at centers with or without on-site surgical back-up, were identified. The primary outcome was all-cause mortality after PCI. Secondary outcomes were rates of emergency CABG and various complications during or after PCI. Odds ratios (OR) with 95% confidence intervals (CI) between with and without on-site surgical back-up were compared.

RESULTS We included 23 high-quality studies that compared clinical outcomes and complication rates of 1,101,123 patients after PCI at centers with or without on-site surgery. For primary PCI for ST-segment elevation myocardial infarction (133,574 patients), all-cause mortality (without on-site surgery vs. with on-site surgery: observed rates, 4.8% vs. 7.2%, pooled OR 0.99, 95% CI 0.91-1.07, p=0.729, I2=3.4%) or emergency CABG rates (observed rates, 1.5% vs. 2.4%, pooled OR 0.76, 95% CI 0.56-1.01, p=0.062, I2=42.5%) did not differ by presence of on-site surgery. For non-primary PCI (967,549 patients), all-cause mortality (observed rates, 1.6% vs. 2.1%, pooled OR 1.15, 95% CI 0.94-1.41, p=0.172, I2=67.5%) and emergency CABG rates (observed rates, 0.5% vs. 0.8%, pooled OR 1.14, 95% CI 0.62-2.13, p=0.669, I2=81.7%) were not significantly different. PCI complication rates (cardiogenic shock, stroke, aortic dissection, tamponade, recurrent infarction) also did not differ by on-site surgical capability. Cumulative meta-analysis of non-primary PCI showed a temporal decrease of the effect size (OR) for all-cause mortality after 2007.



CONCLUSIONS Clinical outcomes and complication rates of PCI at centers without on-site surgery did not differ from those with on-site surgery, for both primary and non-primary PCI. Temporal trends indicated improving clinical outcomes in non-primary PCI at centers without on-site surgery.

CATEGORIES OTHER: Quality, Guidelines and Appropriateness Criteria

KEYWORDS Clinical outcomes, Meta-analysis, Percutaneous coronary intervention

TCT-450

Novel Insight into the "Geographical Miss Phenomenon": Device Motion Indicator, a New Feature to Evaluate Relative Axial Stent Movement inside Coronary Artery and to Optimise its Precise Deployment Site

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BACKGROUND Geographical miss is a descriptive terminology for a poorly deployed coronary stent and the STLLR trial, which looked specifically this issue, proved the incidence is very high, an astonishing 65% ending with a significantly higher risk for restenosis, target-lesion revascularization (TLR), MI, and stent thrombosis. Yet, the mechanism for this shocking stent plaque dissociation rates, remains to be clarified.

METHODS The cyclic movement of the heart and the coronary arteries induces relative axial movement between the artery and a pre-deployed intra-luminal device which may cause mal-positioning of these devices. The exact nature and extent of this phenomenon is not